

GRUPPO MOFIN ALCE

Rapporto di prova / Test report n°: **0316-17** del / of **07.03.'17** Product Code: PRO1401003
 Accettazione / Acceptance n°: **0316** del / of **01.03.'17**
 Cliente / Customer: **Probiotal Healthcare**
 Prelievo effettuato da / Sampled by: **Probiotal** il / on **01.03.'17**
 Descrizione campione / Sample description: Prodotto: *Coltura batterica probiotica allergen free microincapsulata in polvere*
Product: Powder of Allergen free probiotic microencapsulated bacterial culture
L. rhamnosus LR04 AF ID 1132; L. acidophilus LA02 AF ID 1688; L. plantarum LP01 AF ID 1171;
B. breve BR03 AF ID 1270; B. animalis subsp. lactis BS01 AF ID 1195
 Denominazione commerciale / Commercial designation: **MICROBAC**
 Sigla di identificazione / Strain Identification Code: **MXP 50 AF**
 Lotto / Batch: **FL 121-17**
 Data di produzione / Manufacturing date: **01.03.'17**
 se conservato a / if stored at +5° C ± 1° C: **24 mesi dalla data di spedizione / 24 months from date of shipment**
 se conservato a / if stored at ≤ -18° C: **01.03.'27**

Item #4366

NVE #32094

Recal 3/13/2018

BSA
4/30/18

PROVA / TEST	METODO DI PROVA / TEST METHOD	Unità di misura / Unit	RISULTATI / RESULTS	SPECIFICHE / SPECIFICATIONS SCH.T. (MI 0044-45-54) rev. 08
Acqua libera / Free water (Aw)	Met. Int. 201-02		0,081	≤ 0,200
Solubilità in soluzione acquosa / Solubility in aqueous solution	Met. Int. 203-06		parzialm. solubile / partially soluble	parzialm. solubile / partially soluble
Celle vitali / Viable cells	Met Biolab 612 0'	cells/g · 10 ⁹	230	≥ 100
	Met Int 031 0	UFC/g · 10 ⁹	155	≥ 100
Microrganismi contaminanti a 30 C / Contaminant microorganism at 30 C	Met. Int. 004 04	UFC/g	< 100	< 5 · 10 ¹
Coliformi totali e E. coli / Coliform Group and E. coli	AOAC 966.24:1971	MPN /g	< 3	< 3
TYMC (lieviti e muffe / yeast and moulds)	E.P. ed. 9.0	UFC/g	< 200	< 200
Int. rotococcus spp.	Met. Int. 008 01	UFC/g	< 100	< 5 · 10 ²
Stafilococchi coagulanti positivi / Coagula e positive Staphylococcus	UNI EN ISO 6888 1:2004	UFC/g	< 10	< 10
Batteri solfito-riduttori / sulfite reducing bacteria	NFV 08-061:2009	UFC/g	< 10	< 10
Salmonella spp	AFNOR BRD 07/11 12/05	UFC/25g	assente / absent	assente / absent
Listeria monocytogenes	AFNOR BRD 07/04 09/98	UFC/g	assente / absent	assente / absent

Pro-Biotic Blend MXP50

Note: il presente RP: * non può essere riprodotto parzialmente, salvo approvazione scritta della struttura / this test report cannot be partially reproduced, unless approved in writing by the laboratory

Analista / Analyst

Responsabile Controllo Qualità / QC Manager
Dott. ssa Marika Bertamini



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Anaheim, CA 92806 www.pharmachemlabs.com



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Via E. Mattei, 3 Fax: +39.0321492693
28100 Novara (ITALY) www.probiotal.com



MALDI-TOF Identification Report

MATRIX ASSISTED LASER DESORPTION/IONIZATION TIME OF FLIGHT

Customer: Williams, Thomas

Company: NVE Pharmaceuticals

Address: 15 Whitehall Road, Andover, NJ 07821 USA

125 SANDY DRIVE*NEWARK, DE 19713*PH 302-737-4297*FX 302-737-7781*WWW.MIDILABS.COM

Sample Number: 20180315-2976: Probiotic Blend NVE#32094 Lot#FL 121-17-a

Run Date: 3/27/2018 4:53 PM

Library version: (Bruker) 12/19/2013, (MIDI Labs) 9/18/2014

Closest Match: *Lactobacillus plantarum*

Confidence level: Species

Matches:

Rank	Score	Organism	Source
1	2.165	<i>Lactobacillus plantarum</i>	DSM 1055 DSM
2	2.125	<i>Lactobacillus plantarum</i>	DSM 20246 DSM
3	2.117	<i>Lactobacillus plantarum</i>	DSM 2601 DSM
4	2.101	<i>Lactobacillus plantarum</i>	DSM 12028 DSM
5	2.089	<i>Lactobacillus plantarum</i>	DSM 2648 DSM
6	2.040	<i>Lactobacillus plantarum</i>	DSM 13273 DSM
7	2.017	<i>Lactobacillus plantarum</i>	DSM 20205 DSM
8	1.970	<i>Lactobacillus plantarum</i> ssp <i>plantarum</i>	DSM 20174T DSM
9	1.956	<i>Lactobacillus plantarum</i> ssp <i>argentoratensis</i>	DSM 16365T DSM
10	1.954	<i>Lactobacillus plantarum</i>	M7835 MRS

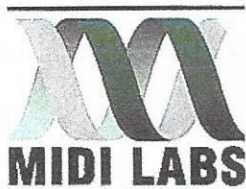
Score Value Key:

Range	Confidence Level
2.000 – 3.000	Species
2.000 – 3.000 multiple species	Species, Closely Related
1.700 – 1.999	Genus
0.000 – 1.699	No Match

Reviewer's Signature: 03-28-18

Clifford Poindexter, Laboratory Manager

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MALDI-TOF Identification Report

MATRIX ASSISTED LASER DESORPTION/IONIZATION TIME OF FLIGHT

Customer: Williams, Thomas

Company: NVE Pharmaceuticals

Address: 15 Whitehall Road, Andover, NJ 07821 USA

125 SANDY DRIVE • NEWARK, DE 19713 • PH 302-737-4297 • FX 302-737-7781 • WWW.MIDILABS.COM

Sample Number: 20180328-3513: Probiotic Blend NVE#32094 Lot#FL121-17-b

Run Date: 3/27/2018 4:53 PM

Library version: (Bruker) 12/19/2013, (MIDI Labs) 9/18/2014

Closest Match: **Lactobacillus**

Confidence level: **Genus**

Matches:

Rank	Score	Organism	Source
1	1.940	Lactobacillus rhamnosus	D528 ZZMK
2	1.845	Lactobacillus rhamnosus	M4282 MRS
3	1.780	Lactobacillus rhamnosus	CIP A157T CIP
4	1.756	Lactobacillus rhamnosus	M4280 MRS
5	1.743	Lactobacillus rhamnosus	DSM 20021T DSM
6	1.732	Lactobacillus rhamnosus	D923 ZZMK
7	1.715	Lactobacillus rhamnosus	D497 ZZMK
8	1.692	Lactobacillus rhamnosus	D121 ZZMK
9	1.641	Lactobacillus casei	DSM 20011T DSM
10	1.604	Lactobacillus paracasei ssp tolerans	DSM 20258T DSM

Score Value Key:

Range	Confidence Level
2.000 – 3.000	Species
2.000 – 3.000 multiple species	Species, Closely Related
1.700 – 1.999	Genus
0.000 – 1.699	No Match

Reviewer's Signature: 03-28-18

Clifford Poindexter, Laboratory Manager

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CLIENT:
 PAMELA HENRIQUEZ/CINDY BEEHNER
 NVE PHARMACEUTICALS
 15 WHITEHALL ROAD
 ANDOVER, NJ 07821

DATE OF REPORT: 3/23/18
 DATE RECEIVED: 3/14/18
 DATE TESTED: 3/15/18
 SAMPLED BY: CLIENT
 METHOD OF ANALYSIS: USP-31 <61>
 USP-40 <62> SALMONELLA

MPL LAB NUMBER: 18C5036
 SAMPLE DESCRIPTION: PROBIOTIC BLEND
 SAMPLE IDENTIFICATION: NVE-32094 LOT #FL-121-17 ITEM #4366

DATA AND FINDINGS:

AEROBIC PLATE COUNT	MOLD PLATE COUNT	YEAST PLATE COUNT
CFU per G	CFU per G	CFU per G
>5.7 x 10 ⁸ (a)	<10	<10

Listeria monocytogenes	Enterococcus
CFU per 25 G	CFU per G
Negative	>5.7 x 10 ⁵ (a)

<i>Salmonella</i>	<i>Staphylococcus aureus</i>	<i>Escherichia coli</i>
Per 10 G (USP-40 <62>)	Per 10 G	Per 10 G
Negative	Negative	Negative

(a) Estimated Count

Patricia O. Griffin, M.S. – Laboratory Director
 Simeon M. Griffin – Quality Assurance Director
 Maureen Tanczos, M.S./Barbara M. Pierce, B.S.

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NOTE: The analyses met the laboratory's quality control requirements unless otherwise indicated. This report shall not be reproduced wholly or in part, without written consent of MPL Laboratories. The results are reported on an "as received" basis unless otherwise indicated. Liability of MPL Laboratories is limited to the cost of the analysis. Any analysis performed is subject to the terms and conditions of MPL Laboratories, an EMSL Analytical, Inc. company, unless otherwise negotiated and agreed upon in writing.



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CLIENT:
DOREEN DULAY/CINDY BEEHNER
NVE PHARMACEUTICALS
15 WHITEHALL ROAD
ANDOVER, NJ 07821

DATE OF REPORT: 4/10/18
DATE RECEIVED: 3/26/18
DATE TESTED: 4/5/18
SAMPLED BY: CLIENT
METHOD OF ANALYSIS: CMMEF CHAPTER 9

MPL LAB NUMBER: 18C8368A

SAMPLE DESCRIPTION: PROBIOTIC BLEND – (RESAMPLE #2) NVE 32094

SAMPLE IDENTIFICATION: LOT #FL-121-17 ITEM #4366

DATA AND FINDINGS:

ENTEROCOCCUS
CFU per G
>57,000 ^(a)

^(a) Estimated Count

Patricia O. Griffin, M.S. – Laboratory Director
Simeon M. Griffin – Quality Assurance Director
Maureen Tanczos, M.S./Barbara M. Pierce, B.S.

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NVE PHARMACEUTICALS
15 WHITEHALL ROAD
ANDOVER, NJ 07821

DATE OF REPORT: 4/10/18
DATE RECEIVED: 3/26/18
DATE TESTED: 4/5/18
SAMPLED BY: CLIENT
METHOD OF ANALYSIS: CMMEF CHAPTER 9

MPL LAB NUMBER: 18C8369A

SAMPLE DESCRIPTION: PROBIOTIC BLEND -- (RETEST #1) NVE 32094

SAMPLE IDENTIFICATION: LOT #FL-121-17 ITEM #4366

DATA AND FINDINGS:

ENTEROCOCCUS
CFU per G
>57,000 ^(a)

^(a) Estimated Count

Patricia O. Griffin, M.S. – Laboratory Director
Simeon M. Griffin – Quality Assurance Director
Maureen Tanezos, M.S./Barbara M. Pierce, B.S.

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RAW MATERIAL CERTIFICATE OF ANALYSIS				
Name: Probiotic Blend		Co-Packer: N/A		Item #: 4366
NVE Receiving #:	Supplier Lot #:		Supplier:	
32094	FL121-17		Pharmachem Laboratories	
Date Received:	Date Sampled:	Container Condition:		Received COA: <input checked="" type="checkbox"/> YES / <input type="checkbox"/> NO
03/13/2018	03/14/2018			

Property Name	Specifications / Acceptable Limits	Analysis Method	Results	Notebook Reference / Initials
Appearance	Off-White to Light Tan Powder	Visual	Off-White Powder	TJW006 p. 82/T W
* Identity of Microorganisms	Positive Identification	MALDI-TOF	Positive ID for Lactobacillus plantarum and Lactobacillus rhamnosus	Attached/T W
Total Plate Count	NMT 10 ⁷ cfu/g	USP	>5.7 x 10 ⁸	Attached/T W
Yeast / Mold Count	NMT 100 cfu/g	USP	<10 cfu/g	Attached/T W
E Coli	Not detected in 10g	USP	Not detected	Attached/T W
Salmonella	Not detected in 10g	USP	Not detected	Attached/T W
* Enterococcus spp.	NMT 100cfu/g	USP	>5.7 x 10 ⁷	Attached/T W
Staphylococcus	Not detected in 10g	USP	Not detected	Attached/T W
Listeria monocytogenes	Not detected in 10g	USP	Not detected	Attached/T W

* See attached information from supplier concerning identity testing and contaminant testing. As precautionary measure all products using this material will include testing for enterococcus sp. CB 04/30/18

Laboratory Notebook Review by/Date:		Cbechner 03/25/18		
Disposition: (Check one)	<input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> HOLD <input type="checkbox"/> REJECT <input type="checkbox"/> RETURN TO SUPPLIER <input type="checkbox"/> DESTROY			
Authorized Signature / Date:		DDulay 04/30/2018		

Prepared by / Date:	Approved by / Date:
J. C. Bechner 09/27/17	Cbechner 09/27/17
Template Form CD051.02 (08/07/17)	Item Specific Form Rev. 4 (09/27/17)